DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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WARNING LETTER

June 13, 2002

President/Owner
Diabetes Tea
P.O. Box 2206
Stow, Ohio 44224

Ref: 02-HFD-312-03

Dear Sir or Madam.

This letter is written in reference to your firm's marketing of the product Overdrive, which, according to your Internet web site, http://www.diabetestea.com, contains, among other ingredients, norephedrine HCl and ephedrine HCl. Statements made on your Internet website indicate that this product is intended for appetite suppression and useful for fat loss.

Although your web site represents this product as a dietary supplement, for example by the statement, "...supplements intended for special dietary use...", this product cannot be so considered because both the ephedrine HCl and the norephedrine HCl used in your product appear to be synthetic compounds that are not derived from any botanical source. Synthetic norephedrine HCl and ephedrine HCl are not plant-derived and cannot, therefore, be considered constituents or extracts of a botanical source. Consequently, FDA has determined that synthetic ephedrine alkaloids are not "dietary ingredients" as defined in the Federal Food, Drug and Cosmetic Act [the Act, Section 201(ff)(1)]. Therefore, products containing synthetic ephedrine alkaloids do not fall under the dietary supplement regulatory scheme.

Based on its intended uses, to affect the structure or function of the body, this product is a drug within the meaning of Section 201(g) of the Act. Such products are considered drugs when their intended use is established by structure/function claims, such as those that appear on your web site. Some of the claims on your Internet web site, http://www.diabetestea.com, from which this product may be ordered, state, for example, "...It's the 'Ferrari' of fat burners...feel energized...burn fat...suppresses appetite...".

As a drug, the labeling claims made for this product subjects it to the requirements for new drugs [Section 201(p) of the Act] because there is no evidence that this product is generally recognized as safe and effective for its claimed uses. Under Section 505(a) of the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application is in effect for such drug. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution violates Section 505 of the Act.

This letter is not intended to be an all-inclusive review of your Internet web site nor all labeling and products your firm markets. The violation of the Act described above is not intended to be an all-inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm, including other products containing synthetic ephedrine alkaloid, are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the FDA without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Ms. Vesna Stanoyevitch, Compliance Officer, at the Food and Drug Administration, Center For Drug Evaluation and Research, Office of Compliance (HFD-310), Metropark North I, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

/s/

David J. Horowitz, Esq.
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration